510(k) Summary

Submitter:	Menicon Co., Ltd. New Business Division 5-1-10, Takamoridai, Kasugai, Aichi 487-0032 JAPAN
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Date Prepared:	June 6, 2014
Trade Name:	Qualis
Classification:	Class II 21 CFR § 884.6160, Assisted Reproduction Labware
Product Code:	MQK
Predicate Device(s):	The subject device is equivalent to the following devices: K112413, Research Instruments Migration Sedimentation Chamber
Device Description:	The Qualis is a sterile, disposable, plastic laboratory dish that contains four chambers connected through micro-channels and is designed to be used in conjunction with commercially available culture medium to selectively separate motile spermatozoa (sperm) for non-motile spermatozoa and cellular debris.
Intended Use:	The Qualis is intended for preparing motile human sperm for use in the treatment of infertile couples by intracytoplasmic sperm insertion (ICSI) fertilization.
Functional and Safety Testing:	To verify that device design met its functional performance and safety requirements, representative sample of the device underwent testing including human sperm survival assay (HSSA) and human sperm motility/morphology.
Conclusion:	Menicon Co., Ltd. New Business Division considers the Qualis to be equivalent to the predicate device listed above. This conclusion is based upon the devices' similarities in principles of operation, technology, materials and indications for use. <u>Substantial Equivalence Discussion</u> • The subject and predicate devices have the same intended use, although different indications. The predicate device is intended to prepare motile sperm for intracytoplasmic sperm injection (ICSI), in vitro fertilization (IVF) and intrauterine insemination (IUI), whereas the subject device is intended for separating motile sperm for ICSI only. The difference does not raise any

concerns because the indication claimed for the subject device falls within the indications covered by the predicate device.

- The subject and predicate devices are based on the same fundamental technological characteristics – natural swimming of sperm, although they have different designs and mechanisms of action. The subject device is designed to separate the motile sperm via laminar flows, whereas the predicate device is designed to separate the motile sperm by gravity drop. However, both devices rely on natural swimming of motile sperm from suspension media into separation media where the motile sperm are collected.

  Effectiveness of the subject device with new design is a concern but can be evaluated by performance testing. The final design validation study demonstrated that the subject device is effective.

- The subject and predicate devices are also different in materials. The subject device is manufactured with cyclo-olefin polymer whereas the predicate device is made of polystyrene. The difference raises a safety concern; however, safety of the subject device can be evaluated by Human Sperm Survival Assay (HSSA). The result of HSSA testing demonstrated that the subject device is safe.

Parameter	Subject device -- Qualis (K133295)	Predicate device -- RI MSC (K112413)
Indications	Intended for preparing motile human sperm for use in the treatment of infertile couples by intracytoplasmic sperm insertion (ICSI) fertilization	Intended to prepare sperm by migration-sedimentation method for the assisted reproductive techniques of intracytoplasmic sperm injection (ICSI), in vitro fertilization (IVF), and intrauterine insemination (IUI)
Design	A disposable culture dish with four chambers connected by micro-channels	A cylindrical container with internal gallery and well. Optically clear, flat base
Mechanism of action	The semen sample is placed in Chamber A and separation medium is placed in Chamber B. Fluids from both chambers flow via the micro-channels into the central micro-channel where the two fluids pass side-by-side in laminar flow. Motile sperm are able to swim across the interface of the laminar flow streams and pass into the separation medium stream but non-motile sperm and debris cannot. Motile sperm that cross into the separation medium flow are carried into Chamber C where they are collected. Non-motile sperm and debris remain in the semen sample flow from Chamber A into Chamber D.	The chamber is pre-loaded with culture medium into which unprepared (raw) sperm is pipetted. During incubation, sperm migrate to the over-laying medium based on their nature swimming nature and fall by gravity into the central well of the chamber for collection.
Material	Cyclo-olefin polymer	Polystyrene

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 18, 2014

Menicon Life Science
% Marcia Palma
Medical Research Regulatory Specialist
NAMSA
4050 Olson Memorial Hwy, Suite 450
Minneapolis, MN 55422

Re: K133295
Trade/Device Name: Qualis
Regulation Number: 21 CFR 884.6160
Regulation Name: Assisted Reproductive Labware
Regulatory Class: Class II
Product Code: MQK
Dated: May 20, 2014
Received: May 22, 2014

Dear Marcia Palma,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301)796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K133295

Device Name

Qualis

Indications for Use *(Describe)*

The Qualis is intended for preparing motile human sperm for use in the treatment of infertile couples by intracytoplasmic sperm insertion (ICSI) fertilization.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Herbert P. Lerner -S
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